EXHIBIT 9

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EDITORIAL

The failed idea of a "gold standard"

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The term "gold standard" is used quite often in medicine [1, 2]. It says that there is a standard that clinicians should follow and that this is the best standard available, backed by solid evidence and broad consensus. "Gold standard" is a historical term borrowed from economists [3]. Gold is a precious metal and has mystical connotations. It implies wealth, power, and security. But as there are other precious metals that are even more expensive, the term "gold standard" should not be taken at face value for three reasons.

First, clinicians are led to think that a procedure with the label "gold standard" is the procedure of first choice and possibly should be applied in all cases [4]. The evidence behind "gold standards" is often incomplete and of insufficient quality. Many systematic reviews close with a statement like "more research is needed". This is certainly true, but it makes one doubt how solid the evidence behind the "gold standard" actually is. In addition, on closer reading, the external validity of many studies is not always clear and the findings cannot be applied in all the cultural and socioeconomic settings in which medicine is practiced.

Second, using the term "gold standard" is tantamount to handing over a weapon of self-destruction to the medico-legal community. We should have learned a lesson from the history of the introduction and application of mesh in pelvic floor reconstructive surgery. The term gold standard was used for Burch colposuspension, for needle procedures, for anterior repair, and many companies tried to establish meshes as the gold standard. Many gold standards were consensus- and not evidence-based. New procedures were introduced with great fanfare and few data; they were proclaimed to be the new standard until they disappeared from many markets almost overnight. Only in hindsight did it become clear that meshes may have a place in reconstructive surgery, but well-executed studies are needed, looking at the whole picture: anatomical results, minor and major complications, economic aspects, and most importantly the benefits to the patient. The same may be happening with abdominal sacrocolpopexy, which often is declared the new standard for apical fixation at the exclusion of procedures employing native tissue with comparable patient satisfaction and fewer major complications. While our debate goes on it is no wonder that lawyers focus on the what we ourselves call a "gold standard" and question alternative procedures.

Third, while gold is known to remain stable over centuries the term "gold standard" has a notoriously short half-life. Like the price of gold, which rises and falls for obvious and less apparent reasons so-called "gold standards" have a tendency to become outdated quickly, never to recover. This is a normal development reflecting the progress of medical and surgical science. As new procedures are introduced and more evidence becomes available "gold standards" lose their glitter and are thrown into the dustbin of medical progress [5]. Most clinicians have seen the coming and going of techniques that are quickly pronounced a "new" standard, only to be replaced by the next and better procedure [6]. Remember what happened to colposuspension?

Is there a solution? We would suggest doing away with the term "gold standard" and replacing it with "current standard."

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Current standard implies that things might be completely different tomorrow—as we know they will—and the term encourages us to consider alternatives and in particular the setting in which we practice medicine. The cost of an operation, the availability of the materials needed for a procedure, and the possibility of managing complications must all be taken account when offering surgery to a patient. What could be considered a standard in one country might be completely out of place in another healthcare environment.

Instead of blindly following a "gold standard," let us look at the evidence ourselves and apply it critically in a specific healthcare setting to the individual patient. Isn't this what evidence-based medicine is all about?

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